UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF PENNSYLVANIA

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| CHRISTOPHER MCNAUGHTON, a Pennsylvania citizen,<br><br>Plaintiff,<br><br>vs.<br><br>UNITEDHEALTHCARE INSURANCE COMPANY, a Connecticut corporation, UNITED HEALTHCARE, INC., a Delaware corporation,<br><br>Defendants. | CIVIL ACTION<br><br>Case No.:<br><br>**DECLARATION OF DR. EDWARD V. LOFTUS, JR. IN SUPPORT OF PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION AND EXPEDITED HEARING** |

I, Edward V. Loftus, Jr., MD, FACP, FACG, AGAF, state:

1. The facts stated in this declaration are based on my own personal knowledge as well as my education, training, and experience as a gastroenterologist in practice at the Mayo Clinic in Rochester, Minnesota. I received my medical degree from the University of Pennsylvania School of Medicine. I completed an internship and residency in Internal Medicine at Temple University, and a fellowship in Gastroenterology at the Mayo Graduate School of Medicine, Mayo Clinic College of Medicine. Attached as Exhibit 1 is a copy of my CV, which is a true and correct representation of my educational background and professional activities.

2. Christopher McNaughton is my patient. He was diagnosed with severe ulcerative colitis in January 2014. Prior to his current treatment, this disease caused McNaughton to report bloody diarrhea up to twenty times a day; severe abdominal pain; severe anemia causing constant fatigue; loss of appetite; significant weight loss and alnutrition; severe inflammatory arthritis which left him unable to walk and required hospitalization; severe, recurrent, life-threatening, deep vein resulting in repeated hospitalizations; repeated fractures and osteopenia; and severe secondary adrenal insufficiency.

3. In 2015, McNaughton was referred to me at the Mayo Clinic in Rochester, Minnesota due to the severity of McNaughton's ulcerative colitis.

4. In October 2018, after repeated failures of other ulcerative colitis medications and doses, I prescribed a combination of Remicade 20 g/kg every 4 weeks and Entyvio 600 mg every 4 weeks to McNaughton. This treatment in these specific doses was and is absolutely medically necessary for McNaughton.

5. United conducted a "peer to peer" review with me on May 12, 2021. After that review, on May 14, 2021, they sent an email to McNaughton indicating that they were denying coverage of the infusions for McNaughton in the 2021-22

plan year, but the statements attributed to me by United in their May 14, 2021 email are an inaccurate account of the peer to peer review. I did not agree that McNaughton's current treatment regime was "not appropriate" and I did not agree to "titrate him down."

6. On May 19, 2021, I wrote a letter stating that McNaughton required the treatments that I prescribed, and that failure to provide these treatments could have "serious detrimental effects on both his short term and long term health and could potentially involve life threatening complications. … McNaughton was on the doses suggested by United [illegible]care before, and they were not at all effective." (Attached as Exhibit 2 is my May 19, 2021 letter.)

7. On June 4, 2021, after being confronted with the false statements in the May 14, 2021 denial, United advised McNaughton that it would not cover his infusions at the required doses as I prescribed. (Attached as Exhibit 3 is the June 4, 2021 denial letter.)

8. Prior to the June 4, 2021 letter, I had explained that McNaughton would suffer "serious", "long term", and "life threatening complications" if United did not provide coverage for the treatments.

9. On June 7, 2021, I sent another letter explaining that I never said the things attributed to me in Dave Opperman's email to McNaughton dated May 14, 2021. (Attached as Exhibit 4 is my June 7, 2021 letter.)

10. As stated above, McNaughton is my patient at the Mayo Clinic in Rochester, Minnesota. I have been managing his ulcerative colitis for the past 6 years. His disease has been severe and difficult to treat.

11. McNaughton has a 7-year history of severe refractory ulcerative colitis, and he had been steroid-dependent despite multiple medications. He is currently on an intensive regimen of Entyvio, Remicade, azathioprine, allopurinol, mesalamine suppositories, and budesonide foam. With this regimen,

is in clinical remission fro his ulcerative colitis. Before beginning his current treatment regimen, McNaughton was hospitalized numerous times with what had the potential to be life-threatening complications. If McNaughton's treatments are interrupted or delayed in any way by United's actions, he would be at substantial risk for loss of response to his current protocol, placing his health in significant danger. Given that Remicade and Entyvio are biologic medications, he cannot just stop and restart or reduce the doses, as there is a high likelihood they would no longer be effective. This is especially problematic for McNaughton, as he has iled numerous other ulcerative colitis medications, and endured significant ng over 5 years before arriving at his current protocol. If McNaughton were not to have his current treatment protocol, or it were to stop being effective, it would put his life at significant risk.

12. It is therefore my medical opinion that McNaughton continue with his current treatment regimen of Remicade 20mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks. The combination of Remicade 20 mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks has been crucial in allowing to finally taper off high dose prednisone after 5 years, and avoid the substantial side effects that come with long term prednisone use. This treatment protocol has helped McNaughton to achieve and maintain his current level of health and avoid frequent and recurring hospitalizations as well as extraintestinal manifestations. The combination of Remicade 20 every 4 weeks and Entyvio 600 mg every 4 weeks was arrived upon after McNaughton failed numerous other treatments over a 5-year period. If McNaughton were to follow the regimen suggested by United Healthcare in the email dated May 14, 2021 ( micade 5 mg/kg every 8 weeks and Entyvio 300 every 8 weeks), it would have serious detrimental effects on both his short term and long term health and could potentially involve life-threatening complications.

McNaughton was on the doses suggested by United Healthcare before, and they were not at all effective.

13. Please note McNaughton has failed all lower doses and combinations of these medications so it is essential that he receive them at the doses they are currently prescribed (Entyvio 600 mg every 4 weeks and Remicade 20mg/kg every 4 weeks).

14. To reiterate, it is my expert medical opinion within a reasonable degree of medical certainty that McNaughton continue with his current treatment of Remicade 20mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks.

15. McNaughton's current treatment regimen is absolutely necessary. In addition, his current treatment meets the following definition of Medical Necessity: "those services or supplies provided or prescribed by a Hospital or Physician which are all of the following: 1) Essential for the symptoms and diagnosis or of the Sickness or Injury; 2) Provided for the diagnosis, or the direct care and treatment of the Sickness or Injury; 3) In accordance with the standards of good medical practice; 4) Not primarily for the convenience of the Insured, or the Insured's Physician; 5) The most appropriate supply or level of service which can safely be provided to the Insured." I told that this definition of Medical Necessity appears in his United insurance policy.

16. McNaughton's current treatment regimen is also not experimental or investigational.

17. I hold all of the opinions expressed in this declaration within a reasonable degree of medical certainty.

I declare under penalty of perjury that the foregoing is t and correct and would testify as to same if called upon as a sworn witness at time of trial.

Executed on this 16th day of September, 2021 at Rochester, Minnesota

Edward V. Loftus, Jr., MD

Sworn to and subscribed
before me this
day of September 16th 2021.

Notary Public

LAWRENCE MINDELA
Notary Public-Minnesota
My Commission Expires Jan 31, 2023

# EXHIBIT 2

Name: Christopher A. McNaughton I DOB: [redacted] I MRN: [redacted] I PCP:

# Letter Details

MAYO CLINIC

200 First Street SW
Rochester, Minnesota 55905

507-284-2511
mayoclinic.org

May 19, 2021
RE: Christopher A. McNaughton
MC#: [redacted]
DOB: [redacted]

To Whom It May Concern:

Christopher McNaughton is a patient under my care at Mayo Clinic in Rochester, Minnesota. I have been managing his ulcerative colitis for the past 7 years. His disease has been severe and difficult to treat.

Chris has a 7-year history of refractory ulcerative colitis, and he had been steroid-dependent despite multiple medications. He is currently on an intensive regimen of Entyvio, Remicade, azathioprine, allopurinol, mesalamine suppositories, and budesonide foam. With this regimen, Chris is in clinical remission from his ulcerative colitis.

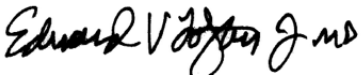
It is therefore my strong recommendation that Chris continue with his current treatment regimen of Remicade 20mg/kg every 4 weeks and Entyvio

600 mg every 4 weeks. The combination of Remicade 20 mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks has been crucial in allowing him to finally taper off high dose prednisone after 5 years, and avoid the substantial side effects that come with long term prednisone use. This treatment protocol has helped Chris to achieve and maintain his current level of health and avoid frequent and recurring hospitalizations as well as extraintestinal manifestations. The combination of Remicade 20 mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks was arrived upon after Chris failed numerous other treatments over a 5 year period. If Chris were to do the regimen suggested by United Healthcare (Remicade 5 mg/kg every 8 weeks and Entyvio 300 mg every 8 weeks), it would have serious detrimental effects on both his short term and long term health and could potentially involve life threatening complications. This would ultimately incur far greater medical costs. Chris was on the doses suggested by United Healthcare before, and they were not at all effective.

To reiterate, it is my strong recommendation that Chris continue with his current treatment regimen of Remicade 20mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks.

Feel free to contact me if you have any questions or require additional information.

Sincerely,



Edward V. Loftus, Jr., MD, FACP, FACG, AGAF
Professor of Medicine
Mayo Clinic College of Medicine
Director, Inflammatory Bowel Disease Interest Group
Division of Gastroenterology and Hepatology
Mayo Clinic
Rochester, Minnesota

*This letter was initially viewed by Christopher A. McNaughton on 5/19/2021 2:46 PM.*

# EXHIBIT 3

UnitedHealthcare

**Student** Resources
P.O. Box 809025
Dallas, TX 75380-9025
1-800-767-0700

June 04, 2021

Christopher Mcnaughton
229 Woodland Dr.
State Colleg, PA 16803

Insured: Christopher Mcnaughton
Insured DOB: [redacted]
Claim#: 20124734-01
SRID#: 8250035
Policy: 20-3694-01
Legal Entity: United Healthcare Insurance Company

Dear Christopher McNaughton:

This is to acknowledge your request for consideration of coverage for your medications, J1745-Remicade 20mg/kg every four weeks and J3380-Entyvio 600mg every four weeks for the 2021-2022 policy term.

As previously communicated to you, your medical records were reviewed to determine whether the medication you have been prescribed is medically necessary. The records have been reviewed three times and the medical reviewers have concluded that the medication as prescribed does not meet the Medical Necessity requirement of the plan. In addition, a peer-to-peer review was conducted between your physician and a medical expert representing our company. Our medical representative determined that use of Remicade and Entyvio together is supported in this case. However, it was also determined that the prescribed dosages for the two drugs are not established when using a dual biologic therapy. The concern from the reviewers is the safety of the prescribed dosage and frequency.

In accordance with the conclusions of the reviewers, the two prescribed medications, Remicade and Entyvio, will not be covered at the prescribed dosage under the Penn State Student plan for the 2021-2022 academic year. Please understand that the reviews have been conducted in advance of you enrolling in the 2021-2022 Penn State student plan to give you an opportunity to make an informed decision about your health insurance coverage for the upcoming academic year.

Please note this is not a treatment decision. Treatment decisions are made between you and your physician. This is a denial for benefits under the plan for the prescribed treatment.

An insured person or their authorized representative may have the right to have this decision review by healthcare professionals who have no association with us when the treatment in question:

1. Is a covered medical expense under the policy; and
2. Is not covered because it does not meet the Company's requirements for medical necessity, appropriateness, healthcare setting, level of care, effectiveness or the treatment is determined to be experimental or investigational.

You have the right to have this decision reviewed by an external independent third party who has no association with us. You or your authorized representative, such as a family member or physician, may request this external review as you have exhausted the internal appeal process.

The insured person or their authorized representative has four (4) months to request an external review of

this final determination. The request for an external review should be made in writing to the Company. When filing a request for an external review you will be required to authorize the release of medical records. If requesting an external review, complete and return the enclosed form along with your written request to:

Claims Appeals
UnitedHealthcare Student Resources
P.O. Box 809025
Dallas, Texas 75380-9025

An insured person or their authorized representative may submit a request for an expedited external review if one of the following applies:

- If the insured person has a medical condition where the time-frame for completion of an expedited internal review or a standard external review would seriously jeopardize the life or health, or jeopardize the insured person's ability to regain maximum function.
- If the denial of coverage is based on a determination that the recommended or requested service or treatment is experimental or investigational and the treating physician certifies in writing that any delay may pose an imminent threat to the insured person's health.
- If the denial of coverage involves an admission, availability of care, continued stay, or health care service for an insured person who has received emergency services, but has not been discharged from a facility.

An expedited external review may not be provided for retrospective adverse determinations

There may be other resources available to help understand the appeals process. For questions about appeal rights or an adverse benefit determination, the state department of insurance may be able to assist at:

Pennsylvania Insurance Department
Consumer Services
1209 Strawberry Square
Harrisburg, PA 17120
Phone: (717) 787-2317
(877) 881-6388
Website: www.insurance.pa.gov

In addition, and under limited circumstances, a request for an expedited external review may be requested. For details, contact our Customer Service Department at 800-767-0700.

Sincerely,

Lisa Dealy
Manager of Appeals and Reviews
**Student** Resources

Enclosures: Language Assistance Program (Insured/Member Only )
Non Discrimination Notice (Insured/Member Only)
External Review Request Form
Pennsylvania Appeal Rights

Cc: Christopher Mcnaughton

LD/Vk

# EXHIBIT 4

MAYO CLINIC
200 First Street SW
Rochester, Minnesota 55905

507-284-2511
mayoclinic.org

June 7, 2021
RE: Christopher A. McNaughton
MC#: [redacted]
DOB: [redacted]

To Whom It May Concern:

The statements from United Healthcare/First Risk Advisors contained in the email from Dave Opperman (President First Risk Advisors) dated Friday May 14, 2021, are an inaccurate account of the Peer-to-Peer Review that took place Wednesday May 12, 2021. I did not agree that Chris' current treatment regimen was "not appropriate," and I did not agree to "titrate him down." As detailed in my letter dated May 19, 2021, I strongly recommend that Chris continue with his current regimen of Remicade 20 mg/kg every 4 weeks and Entyvio 600 mg every 4 weeks. I emphasized this during the Peer-to-Peer Review. What United Healthcare/First Risk Advisors is alleging is an inaccurate representation of what took place during the Peer-to-Peer Review.

Feel free to contact me if you require additional information.

Sincerely,

Edward V Loftus MD

Edward V. Loftus, Jr., MD, FACP, FACG, AGAF
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Mayo Clinic College of Medicine
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